

Feb-18-2004 14:42

From-BROWDY NEIMARK

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T-647 P.001

F-465

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USSN - 09/845,917

No. of pages (including this cover sheet):

11

FROM:

Lisa Staley for Iver Cooper

Remarks:

*Please make sure we are not  
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APPLICATION/PATENT NO: 09/845,717  
DOCKET NO: Nielsen=3B

CONF. NO.: 3818  
CLIENT CODE: PLDU

THE PATENT AND TRADEMARK OFFICE STAMP  
HEREON ACKNOWLEDGES RECEIPT OF THE  
FOLLOWING PAPERS:

- ☒ FEES \$ 82.00  
☒ PTO FORM 2038 ☐ (CH. #         )  
☒ EXTENSION OF TIME (          MONTHS)  
☒ TRANSMITTAL LETTER  
☐ MISSING PARTS RESPONSE WITH DECL  
☒ AMENDMENT/RESPONSE (circle one)  
☒ PRELIMINARY 2nd ☐ SUPPLEMENTAL  
☐ APPLICATION DATA SHEET  
☒ RESTRICTION/ELECTION REPLY  
☐ SEQUENCE LISTING ☐ WITH DISK  
☐ RCE TRANSMITTAL  
☐ NOTICE OF APPEAL  
☐ APPEAL BRIEF (TRIPPLICATE)  
☐ REPLY BRIEF (TRIPPLICATE)  
☐ OTHER

-   
☐ ASSIGNMENT  
☐ INFORMATION DISCLOSURE STATEMENT  
☐ FORM SB08A &          PATENTS/PUBS  
☐ PRIORITY DOCUMENT(S) NO.           
☐ DECLARATION UNDER §           
☐          SHEETS OF FORMAL DRAWINGS  
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Feb-18-2004 14:42

From-BROWDY NEIMARK

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T-647 P.004/011 F-465

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

In re Application of: NIELSEN, et al.

Serial No.: 09/845,717

Filed: May 2, 2001

For: METHODS FOR TREATMENT OF DISEASES ASSOCIATED WITH...

Confirmation No.: 3818

Art Unit: 1647

Examiner: DEBERRY, REGINA

Washington, D.C.

Atty.'s Docket: NIELSEN-3B

Date: December 2, 2003

U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, Virginia 22202

Sir:

Transmitted herewith is an ☒ Election with Traverse & Preliminary Amendment No. 2 in the above-identified  
☐ Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.

☒ Small entity status of this application under 37 CFR 1.9 and 1.27 has been previously asserted.

☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.

☐ No additional fee is required.

The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)		Small Entity		Other Than a Small Entity	
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra		Rate	Additional Fee	Rate	Additional Fee
Total	23	Minus	20	3		x 9	\$27.00	x16	\$
Indep.	3	Minus	4	0		x43	\$	x86	\$
First Presentation of Multiple Dependent Claim						145	\$	+290	\$
TOTAL ADDITIONAL CLAIMS FEE							\$27.00	Total	\$

\* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col.1 of a prior amendment of the number of claims originally filed.

☒ Conditional Petition for Extension of Time

If any extension of time for a response is required applicant requests that this be considered a petit

☒ It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity  
Response Filed Within  
☒ First - \$ 55.00  
☐ Second - \$ 210.00  
☐ Third - \$ 475.00  
☐ Fourth - \$ 740.00  
☐ Fifth - \$1005.00

Other Than Small Entity  
Response Filed Within  
☐ First - \$ 110.00  
☐ Second - \$ 420.00  
☐ Third - \$ 950.00  
☐ Fourth - \$1480.00  
☐ Fifth - \$2010.00

☐ Less fees (\$) already paid for months extension of time on

☐ Please charge my Deposit Account No. 02-4035 in the amount of \$\_\_\_\_\_. A duplicate copy of this sheet is attached.

☐ A check in the amount of \$\_\_\_\_\_ is attached (check no. \_\_\_\_\_).

☒ Credit Card Payment Form, PTO-2038, authorizing payment in the amount of \$82.00 is attached.

☒ The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR Section 1.16 and all patent processing fees under 37 CFR Section 1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR Section 1.18.

02/20/2004 TBESHAH1 00000065 09845717

02 FC:2251

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By:   
EVER P. COOPER  
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**COPY**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1647
NIELSEN, et al.	)	Examiner: DEBERRY, REGINA
Serial No.: 09/845,717	)	Washington, D.C.
Filed: May 2, 2001.	)	December 2, 2003
For: METHODS FOR TREATMENT	)	Docket No.: NIELSEN=3B
OF DISEASES ASSOCIATED	)	Confirmation No.: 3818
WITH INFLAMMATION...	)	

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Arlington, Virginia 22202

S i r :

1. Applicants have, by a separate paper filed on even date herewith, filed a preliminary amendment adding new claims 19-24. These claims are directed to subject matter generically covered by claim 1.

2. The restriction requirement is fatally defective in that it does not specify all of the subject matter claimed. Thus, group I relates to treatment of conditions caused by a cancer or a premalignant disorder, and group II to the treatment of conditions caused by infections, yet claims 1-5, 8-10, 13, and 16-18 all cover treatment of conditions with other causes. Nor is this additional coverage purely formal; alternative causes are disclosed at pages 5-7 and 11-14. The restriction, as presently phrased, at least nominally denies Applicants to prosecute the opportunity to elect any invention encompassed by claim 1 which is not directed to treatment of cancer or infection. The restriction is also defective in that it fails to address claim 18.

3. Applicants wish to elect with traverse to prosecute at least the invention defined by new claim 20, i.e., treatment of inflammation caused by chronic pulmonary obstructive disease (COPD).

If such election is not possible, Applicants wish to elect with traverse to prosecute at least the invention defined by new

USSN - 09/845,717

claim 23, which relates to conditions caused by chemical and physical trauma. Cigarette smoke is the principal cause of COPD, and inflicts both chemical trauma (toxic chemicals including carbon monoxide, nicotines, tars) and physical injury (obstruction of airways by smoke particles). If, and only if the above elections are deemed nonresponsive, we elect group II with traverse.

4. The restriction is also traversed because the Examiner has not demonstrated either that groups I and II are distinct, or that it would be a serious burden to search both.

With regard to distinctness, the Examiner overlooks the point that what is being treated is an inflammatory condition. It should not matter whether that inflammation arises as a result of cancer, infection, or any other cause. Aspirin is given for pain caused by a multitude of different diseases.

With regard to serious burden, the Examiner assigns both I and II to 514/2, and claims 1 and 3 are in both groups. If claims 1 or 3 are patentable, there would be no need to search specific causative diseases.

The inclusion of both cancer and infection in the same computerized literature search on Applicants' therapeutic entity is trivial; it is just a matter of adding a search term.

5. We do not understand the rationale by which claims 2, 5 and 8-10 are assigned only to group II, and claims 3, 4, 13, 16 and 17 are assigned only to group I. These claims are not limited to either (I) cancer or (II) infection.

Respectfully submitted,

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